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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,980	12/14/2001	Jeremy J. Nathanson	DJORTH.120A	2400
32361	7590	06/16/2004	EXAMINER	
GREENBERG TRAUIG, LLP			MELSON, CANDICE C	
885 3RD AVENUE			ART UNIT	PAPER NUMBER
NEW YORK, NY 10022			3732	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

08

Office Action Summary	Application No. 10/021,980	Applicant(s) NATHANSON ET AL.	
	Examiner Candice C. Melson	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-28 and 33-36 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 29-32 and 37-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, Claim 41 states that the distal plate is pivotable relative to the slide, which was not previously disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, 29-32 and 37-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Incavo et al (USPN 5,827,286) in view of Nakajima (USPN 6,335,036). Incavo et al disclose "an internal osteotomy fixation device 2" comprising "a distal plate 4" including a channel. In particular, "the distal plate 4" has "a second end 14, with the second end having an opening that receives the slide 6" (column 4, lines 64-66). As shown in Fig. 4, "slide 6" is translatable with respect to the "distal plate 4" along a first axis and the "slide 6" has ratchet teeth on a first surface. "Ratchet arm 16" is fixed to "distal plate 4" and includes teeth

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configured to engage the slide ratchet teeth. "In one embodiment, the ratchet arm 16 will be a pawl and groove/tooth 25 type of device that will allow advancement of the slide 6 in a first direction but will preclude direction in the opposite movement so that the slide 6 can only be advanced and not retracted" (column 5, lines 3-9). Finally, the osteotomy device 2 also includes a "proximal plate 18". Incavo et al does not disclose the proximal plate 18 hingedly connected to the slide 6. As to newly amended Claims 1, 7, 29, and 32 the first surface of the "slide 6" having ratchet teeth comprises a posterior surface of "slide 6" when the device is implanted.

Furthermore, "distal plate 4" comprises a second channel as shown in Fig. 1A in which "ratchet arm 16" is disposed for movement along an anterior-posterior plane. Furthermore, as to Claims 1 and 2, Nakajima teaches a "bone adjuster 20" with "a first plate 22 attached to one of opposed bone fragments to be adjusted and a second plate 24 attached to the other" (column 3, lines 23-26). "The first plate 22 has a screw-in connecting portion 34 which has a screw hole for accepting the adjusting shaft 26. The screw-in connecting portion 34 is connected to the mounting plate 28 via a hinge 36 so to conform with various shapes of the skeletal frame to be adjusted, so that it is pivotable with the hinge 36 as an axis, enabling support of the adjusting shaft 26 at an appropriate angle" (column 3, lines 39-45). As to Claims 3, 37, 39, and 42, Incavo et al disclose "the slide 6, which is part of the proximal plate 18, contains a bend or curve, with the bend being an angle of deflection represented by the numeral 28. The angle of deflection 28 represents the general contour of the tibia. The angle of deflection may be varied depending on the particular contour of the patient's tibia" (column 5, lines 30-36). As a matter of obviousness, this bend or curve may also be present in the distal plate 4 in addition to or instead of the proximal plate 18. With respect to Claims 4, 38, 40, and 43, the distal plate comprises through-

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holes 10,12 and the proximal plate comprises through-holes 24,26 each adapted to receive a bone screw for securing the device to a patient's bone. As to Claim 6, as best shown in Fig. 1A, the ratchet arm 16 is disposed within a second channel in the posterior surface of the distal plate. Regarding Claim 7, Nakajima teaches the proximal plate includes a first portion 28 defining a first plane and a ledge 22 defining a second plane generally perpendicular to the first plane. Regarding Claim 8, Fig. 3A shows a proximal surface of the ledge 22 abuts a distal surface of a proximal bone segment when the device is implanted within the patient. As to Claim 41, Incavo et al discloses "ratchet arm 16" which is disposed on "distal plate 4" is pivotable relative to the "slide 6" about a second axis that is substantially parallel to a first axis. It would have been an obvious to one of ordinary skill in the art at the time the invention was made to incorporate the hinge feature as taught by Nakajima in order to provide a fixation device capable of adjusting to conform to various skeletal frames and thereby being capable of being used for a wider range of patients.

Allowable Subject Matter

Claims 9-28,33-36 are allowed.

Response to Arguments

Applicant's arguments filed 03/16/04 have been fully considered but they are not persuasive. Applicants submit that "there would be no motivation for one skilled in the art to

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combine the disparate references". Examiner asserts that the device as claimed by Nakajima is merely used as a teaching reference to show that it is known in the art to connect portions of a bone adjuster, specifically a plate and slide portion via a hinge to provide a fixation device capable of conforming better to a variety of skeletal frames. Further, Applicants state that the movement of the ratchet as disclosed by Incavo et al is lateral where the ratchet of the present invention has forward and backward movement. Examiner further asserts that these terms are dependent of the viewpoint of the surgeon. Specifically, Examiner takes forward to be into the page and backward to be out of the page which Incavo et al clearly discloses. In light of these features and the features previously rejected, the rejection of Claims 1-4,7-8,29-32 and 37-43 remain rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

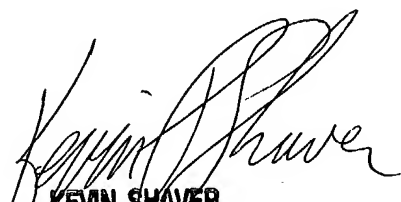
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Melson whose telephone number is (703) 305-8128. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Candice C. Melson



KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700